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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,398	01/02/2002	K. Ranji Vaidyanathan	003248.00041	8382

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EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,398

Applicant(s)

VAIDYANATHAN ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 23, 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10 and 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-15, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 23, 2004 have been fully considered but they are not persuasive.

Contrary to the Applicant's arguments, the composite of Lee et al. is disclosed as capable of load-bearing support (column 12, lines 23-48).

Regarding Vyakarnam et al., the Applicant states that the structures of Vyakarnam et al. "are not suitable for implants comprised of a thermoplastic material that provides load bearing support for natural bone structures." MPEP 716(C) states, "The arguments of counsel cannot take the place of evidence in the record." The Applicant fails to give reason why the structures are not suitable, only arguing that one skilled in the art would look to the disclosure in Vyakarnam et al.

Boltong does not teach away from the present invention. Boltong states:

"For the time being, the inventor does not have any evidence that calcium orthophosphate cements are desirable for load supporting applications. However, when reaching a higher development, a minimum breakage resistance will have to be formulated."

The lack of evidence at the time of invention does not constitute a teaching away. In addition, it is only the use of TGF-beta that is combined with Lee et al., not the calcium orthophosphate cement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8 and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by

Lee et al. (6,027,742) as cited in Applicant's IDS. Lee et al. discloses a biocompatible

implant for surgical implantation comprising: a matrix comprising a resorbable

thermoplastic-ceramic composition (i.e. polymethylmethacrylate-ceramic, col. 12, lines

59-67), for enhancing bone growth adjacent the composition, wherein the implant

provides mechanical support for natural bone structure for a predetermined period of

time to allow the natural bone structure to grow adjacent the material (col. 7, lines 46-

52). The polymer, although poorly resorbable, is resorbable at a slow rate while the

ceramic "growth-enhancing portion" resorbs at a faster rate (9 col. 12, lines 59-67). The

ceramic includes a calcium source (apatitic calcium phosphate). The polymer-ceramic

composition may include copolymers of polylactic acid and polyglycolic acid (col. 9,

lines 36-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (6,027,742) as above in view of Vyakarnam et al. (6,534,084). Lee et al. discloses an implant comprising a thermoplastic material, that can be coated with a ceramic composition (col. 9, lines 34-35) however Lee et al. fails to disclose a specific porosity and pore size. Vyakarnam et al. teaches an implant having a porosity of 50-60% and pores sized between about 150 to about 400 microns, which would be similar to the naturally occurring structure (col. 5, line 66- col. 6, line 41). It would have been obvious to one of ordinary skill in the art to combine the teaching of an implant having a porosity of 50-60% and pores sized between about 150 to about 400 microns, as taught by Vyakarnam et al., to an implant comprising a thermoplastic material as per Lee et al., in order to better approximate the naturally occurring structure.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (6,027,742) as above in view of Boltong (5,605,713). Lee et al. discloses an implant comprising a thermoplastic-ceramic material and a growth-enhancing composition, however Lee et al. fails to disclose the growth-enhancing composition comprising a transforming growth factor. Boltong teaches a ceramic composition comprising a transforming growth factor (TGF-beta) with the aim of stimulating bone growth (col. 5, lines 44-48). It would have been obvious to one of ordinary skill in the art to combine the teaching of a ceramic composition comprising a transforming growth factor, as taught by Boltong, to an implant comprising a thermoplastic-ceramic material and a growth-enhancing composition as per Lee et al., in order to stimulate bone growth.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

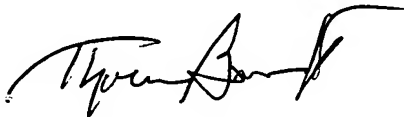
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Thomas Barrett', with a stylized flourish at the end.

Thomas Barrett